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Registration Decision RD2012-23

Fluoxastrobin Technical Fungicide

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Registration Decision for Fluoxastrobin Technical Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Fluoxastrobin Technical Fungicide and Evito 480 SC Fungicide containing the technical grade active ingredient fluoxastrobin to control or suppress certain diseases in wheat, barley, corn (field, seed and sweet), soybean, potato, tomato, pepper, strawberry and turf. In addition, an import maximum residue level (MRL) on celery is being granted.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-07, *Fluoxastrobin Technical Fungicide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for fluoxastrobin and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-07. This decision is consistent with the proposed registration decision stated in PRD2012-07.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-07, *Fluoxastrobin Technical Fungicide* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Fluoxastrobin?

Fluoxastrobin is the fungicidal active ingredient in Evito 480 SC Fungicide. Evito 480 SC Fungicide is a foliar applied, translaminar, systemic fungicide with preventative activity against diseases on wheat, barley, corn, soybean, potato, tomato, pepper, strawberry, and turf. It acts on pathogen cells by inhibiting fungal respiration, which in turn inhibits spore germination, spore penetration and fungal growth.

Health Considerations

Can Approved Uses of Fluoxastrobin Affect Human Health?

Fluoxastrobin is unlikely to affect your health when used according to label directions.

Potential exposure to fluoxastrobin may occur through the diet (food and water) or when handling and applying the product or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the active ingredient fluoxastrobin was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. Fluoxastrobin was minimally irritating to the eyes and non-irritating to the skin. Fluoxastrobin did not cause allergic skin reactions. Consequently, no hazard signal words are required on the label.

The acute toxicity of the end-use product Evito 480 SC Fungicide, containing fluoxastrobin, was low via oral, dermal and inhalation routes. Evito 480 SC Fungicide was non-irritating to the eyes and slightly irritating to the skin. Evito 480 SC Fungicide did cause allergic skin reactions in laboratory animals. Consequently, the hazard signal words "Potential Skin Sensitizer" are required on the product label.

Health effects in animals given repeated doses of fluoxastrobin included effects on the liver, kidneys, urinary system and blood calcium levels. Fluoxastrobin did not damage genetic material or cause cancer at doses that were relevant to human risk assessment. There was no indication that fluoxastrobin caused damage to the nervous system or immune system. Fluoxastrobin did not cause birth defects in animals and there were no effects on the ability to reproduce.

When fluoxastrobin was given to pregnant or nursing animals effects on the developing fetus and juvenile animal were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to fluoxastrobin than the adult animal.

The risk assessment protects against the effects of fluoxastrobin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children (1–2 years old), the subpopulation which would ingest the most fluoxastrobin relative to body weight, are expected to be exposed to less than 46% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fluoxastrobin is not of concern for all population sub-groups. There is no evidence that fluoxastrobin is carcinogenic; therefore, a cancer dietary exposure assessment was not required.

Animal studies revealed no acute health concerns. A single dose of fluoxastrobin is not likely to cause acute health effects in the general population (including infants and children). An acute reference dose was not established; therefore, an acute dietary intake estimate was not required.

The *Food and Drugs Act)* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States and Canada using fluoxastrobin on corn (field and sweet), wheat, barley, soybean, potato, tomato, pepper, strawberry and celery are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Risks in Residential and Other Non-Occupational Environments are Not of Concern

Individuals may come into contact with Evito 480 SC Fungicide when contacting commercially treated turf or picking strawberries at pick-your-own operations. Risks to these individuals are not of concern when label directions are followed.

Occupational Risks From Handling Evito 480 SC Fungicide

Occupational risks are not of concern when Evito 480 SC Fungicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Evito 480 SC Fungicide, as well as field workers, re-entering freshly treated fields can come in direct contact with fluoxastrobin residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Evito 480 SC Fungicide must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical resistant gloves. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Fluoxastrobin Is Introduced Into the Environment?

When fluoxastrobin is applied as a fungicide on turf and field crops, it can find its way into soil and water. Fluoxastrobin tends to adsorb to soil and sediment and does not leach appreciably. It is considered persistent in conditions relevant to the Canadian environment and is expected to carry-over to the next growing season.

Fluoxastrobin presents negligible risks to terrestrial plants, earthworm, bees, birds and small mammals, at the proposed use rates. Studies conducted on artificial substrates, however, suggest that fluoxastrobin could pose a risk to beneficial predatory and parasitic arthropods. Fluoxastrobin could also pose a risk to freshwater algae, invertebrates, fish and amphibians; and to marine algae and invertebrates. In order to minimize the potential for exposure resulting from off-field drift, no-spray buffer zones will be required between the treated area and downwind aquatic habitats.

Value Considerations

What Is the Value of Evito 480 SC Fungicide?

Fluoxastrobin is a preventative fungicidal active ingredient effective in the control or suppression of commercially important diseases in various field crops horticultural crops and turf.

As the active ingredient in Evito 480 SC Fungicide, fluoxastrobin provides an effective tool for the management of a range of commercially important diseases including rusts, powdery mildew, blights, frogeye leaf spot, anthracnose and dollar spot. The product is applied as a preventative treatment on wheat, barley, corn, soybean, potato, tomato, pepper, strawberry and turf. As a new active ingredient in the class of strobilurin fungicides, Evito 480 SC Fungicide will provide increased competition in the Canadian agricultural fungicide market.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Evito 480 SC Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The label must include the following restriction for wheat forage: "If wheat forage will be harvested, make only one application."

Because there is a concern with users coming into direct contact with Evito 480 SC Fungicide on the skin or through inhalation of spray mists, anyone mixing/loading and applying Evito 480 SC Fungicide must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves. In addition, standard label statements to protect against drift during application are required.

Environment

To protect sensitive aquatic species from the use of fluoxastrobin, mitigation measures are recommended. These include adding precautionary statements to the label regarding environmental hazards and the directions for use, as well as no-spray buffer zones of up to 1 m for freshwater habitats and 10 m for marine habitats to mitigate potential exposures via spray drift.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-07, *Fluoxastrobin Technical Fungicide)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.